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(12) **United States Patent**
Dominguez et al.(10) **Patent No.:** **US 10,369,500 B2**(45) **Date of Patent:** ***Aug. 6, 2019**(54) **FAT PROCESSING SYSTEM**(71) Applicant: **Allergan, Inc.**, Irvine, CA (US)(72) Inventors: **Zachary Dominguez**, Santa Barbara, CA (US); **Justin Schwab**, Santa Barbara, CA (US); **Tiago Bertolote**, Geneva (CH); **Jason Metzner**, Carpinteria, CA (US); **Ethan Franklin**, Santa Barbara, CA (US)(73) Assignee: **Allergan, Inc.**, Irvine, CA (US)

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This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

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(51) **Int. Cl.****B01D 33/00** (2006.01)**A61L 27/36** (2006.01)**B01D 17/00** (2006.01)**B01D 33/01** (2006.01)**A61M 1/00** (2006.01)(52) **U.S. Cl.**CPC **B01D 33/00** (2013.01); **A61L 27/3604** (2013.01); **A61L 27/3683** (2013.01); **B01D 17/08** (2013.01); **B01D 17/10** (2013.01); **B01D 33/01** (2013.01); **B01D 33/0183** (2013.01); **A61M 1/0005** (2013.01); **A61M 2202/08** (2013.01); **B01D 2221/10** (2013.01)(58) **Field of Classification Search**CPC .. A61M 1/0005; A61M 3/005; A61M 5/2066; A61M 5/2448; A61M 5/284; A61M 5/31596; A61M 5/3294; B01D 17/08; B01D 17/10; B01D 33/00; B01D 33/01
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Primary Examiner — Renee Claytor*Assistant Examiner* — Susan E. Fernandez(74) *Attorney, Agent, or Firm* — Nathan S. Smith; Danaei N. Mhembe; Morgan, Lewis & Bockius LLP(57) **ABSTRACT**

Methods and devices for treating lipoaspirate for use in fat grafting procedures are provided and generally include a canister for containing lipoaspirate, a separation mechanism structured to separate both oils and other materials from cellular components of lipoaspirate contained in the canister. The separation mechanism includes filters having different filtering capacities, for example, different pore sizes.

13 Claims, 6 Drawing Sheets

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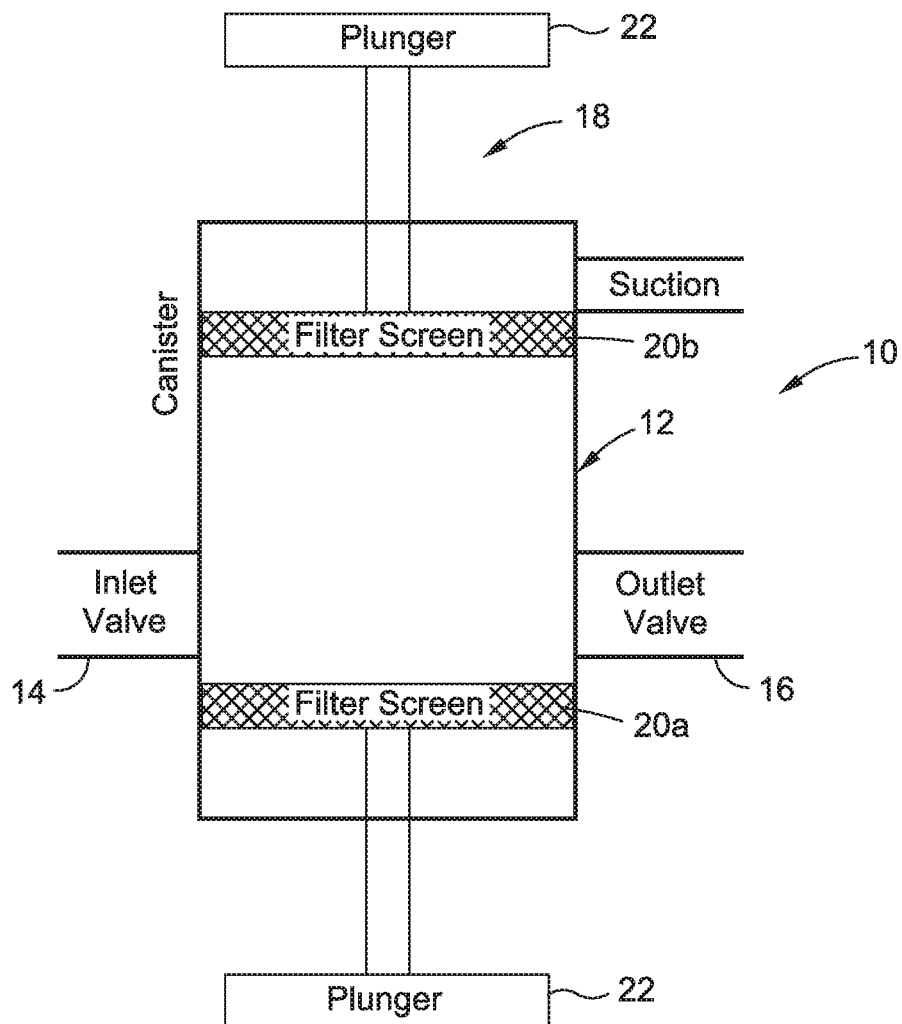


FIG. 1

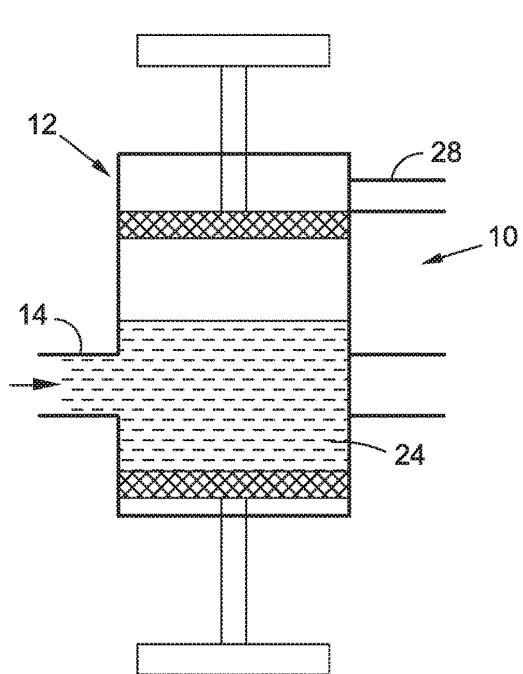


FIG. 2A

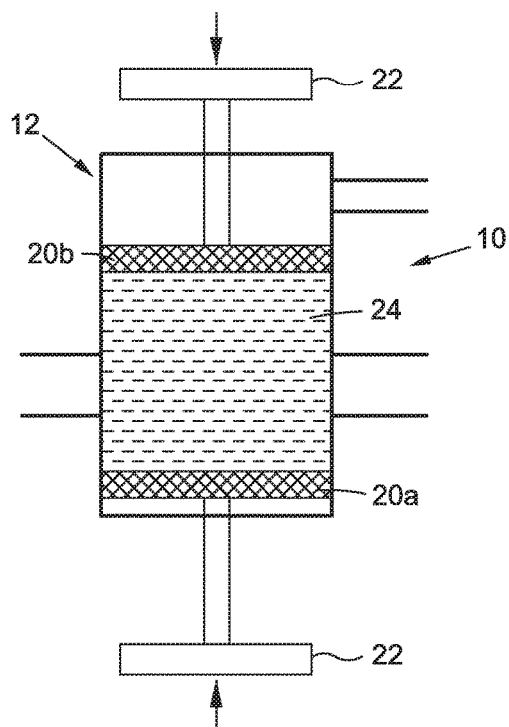


FIG. 2B

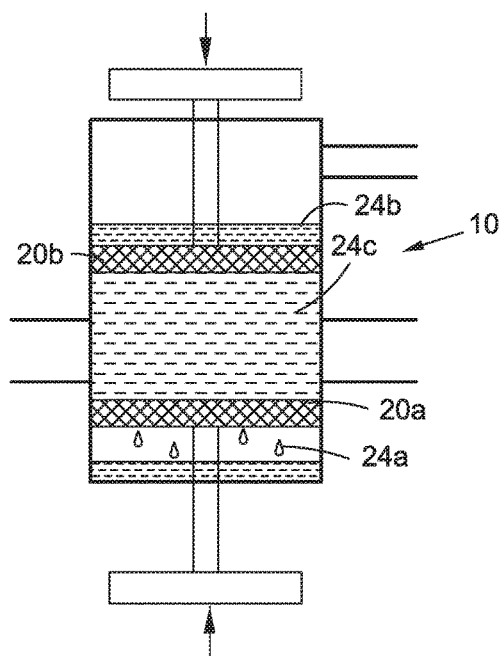


FIG. 2C

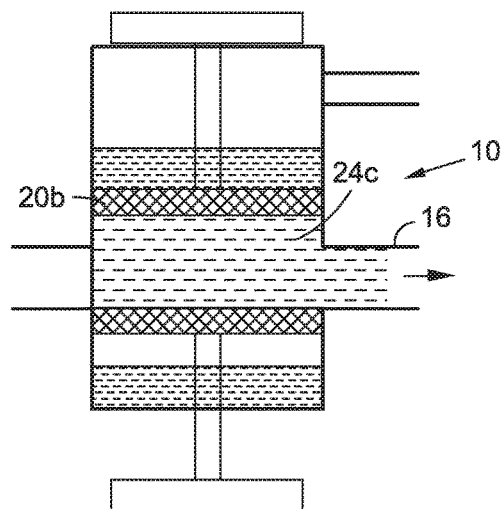


FIG. 2D

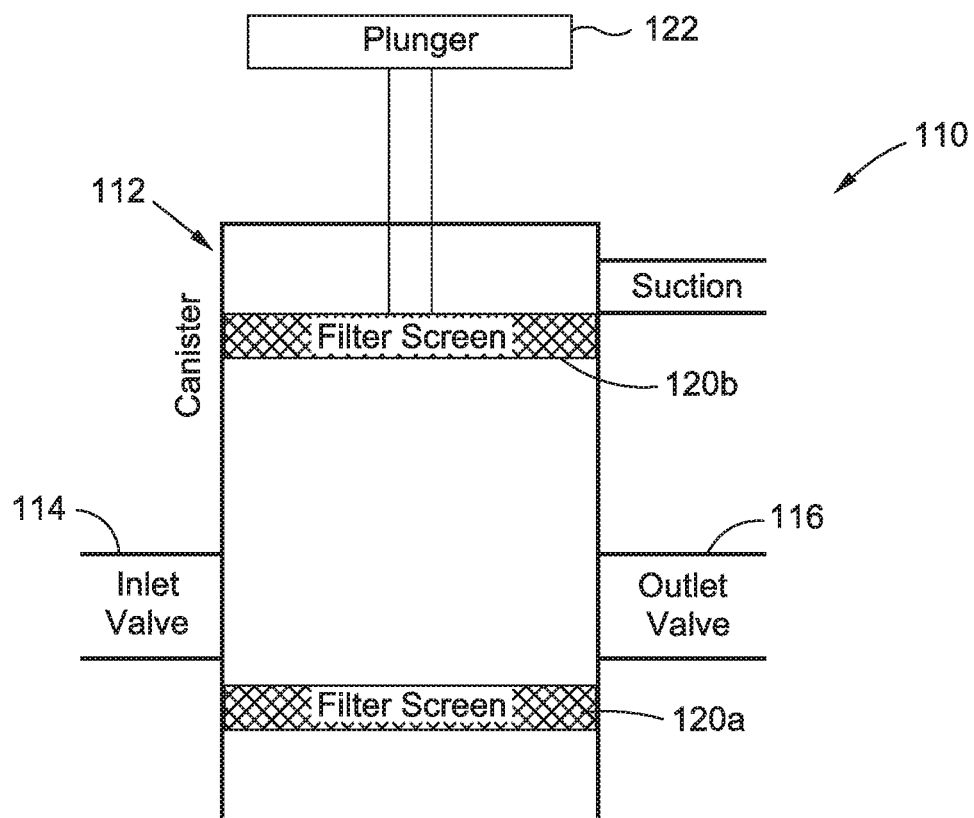


FIG. 3

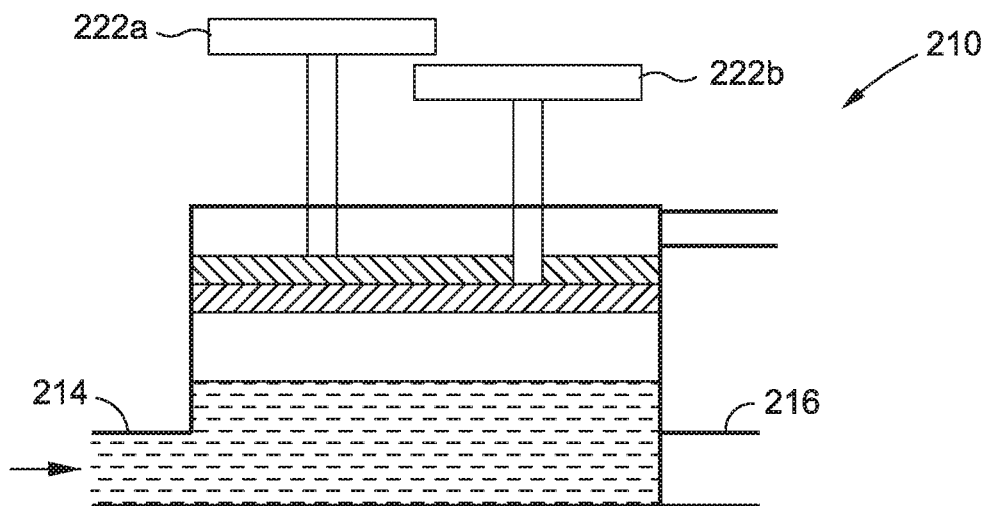


FIG. 4

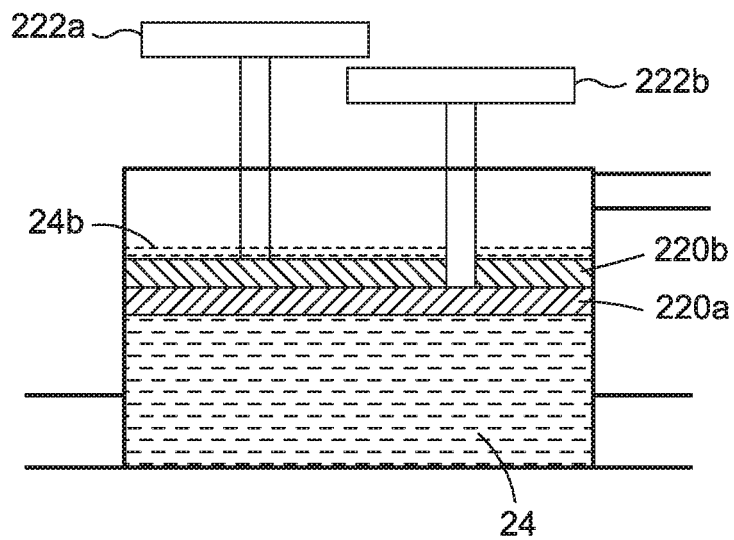


FIG. 4A

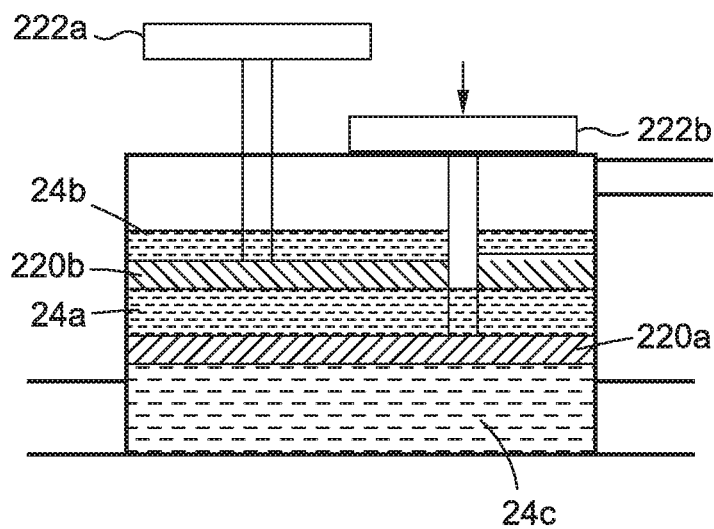


FIG. 4B

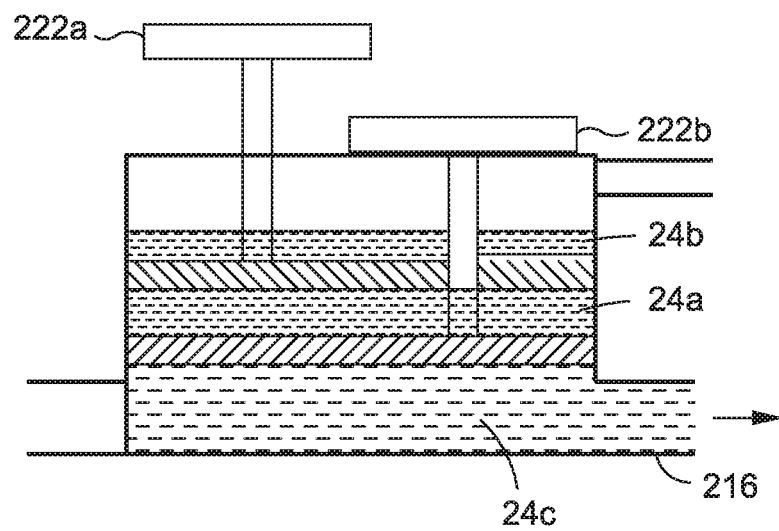


FIG. 4C

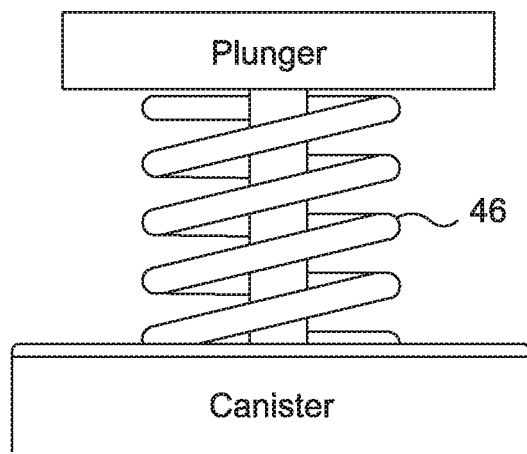


FIG. 5

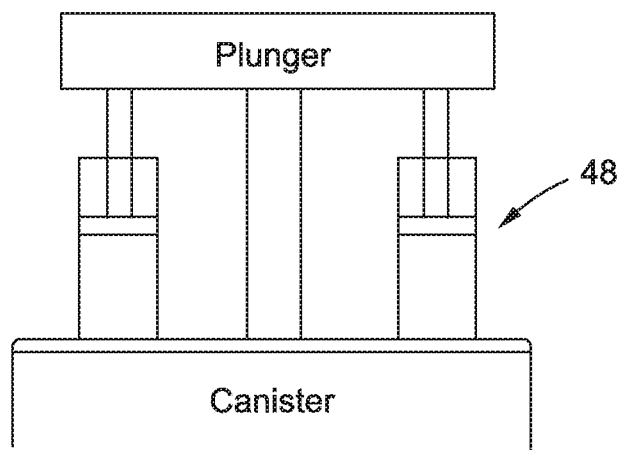


FIG. 6

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FAT PROCESSING SYSTEM**CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. patent application Ser. No. 14/044,594, filed Oct. 2, 2013 the entire disclosure of which is incorporated herein by this specific reference.

BACKGROUND

The present invention generally relates to fat grafting and more specifically relates to a system for processing fat prior to reintroduction into the body.

Autologous fat transfer (AFT), also known as fat grafting, is a process by which fat is harvested from one part of a human body and injected into another part of the same person's body where additional bulk may be needed or desired for cosmetic and/or aesthetic purposes. Clinical applications for autologous fat transfer are expanding rapidly with recent reported use in breast reconstruction and augmentation, buttock enhancement, treatment of congenital tissue defects, facial reconstruction, and skin rejuvenation. Although this is a very attractive approach and there is an increased trend in replacement of soft tissue volume with AFT, typical survival rates of grafted fat may be poor and overall results may not be satisfactory.

WO 2008/148071 discloses kits, tools, and methods are described for harvesting, processing, and using injectable dermis in volume filling procedures.

WO 2009/003135 discloses system for harvesting fat through liposuction, concentrating the aspirate so obtained, and then re-injecting the concentrated fat into a patient.

There still remains a need for improved systems and methods for processing harvested fat for later use in fat grafting procedures.

SUMMARY

The present invention generally comprises a device or system that is structured to be useful for separating unwanted fluids/materials from a sample of lipoaspirate. The resulting cellular material is subsequently used for reintroducing into the body for augmentation or tissue replacement.

During fat grafting procedures, adipose tissue is removed from the body, for example, using an aspirating device, and reintroduced into another part of the body, for example, by means of a syringe. The lipoaspirate initially includes several types of material, for example, undamaged and damaged fat cells, oils, blood cells, intracellular fluids and other materials, some of which may are not ideally suited for reintroduction into the body, for example, for reasons such as safety and graft efficacy.

In general, the three main types of material that comprises the lipoaspirate are viable fat cells, blood/tumescent fluid, and oil (ruptured and/or nonviable fat cells). The present devices and systems are effective to separate at least two or three of these components to achieve a product comprising primarily undamaged adipose and stem cells.

Accordingly a device is provided for treating or processing lipoaspirate for use in fat grafting procedures.

The device comprises, for example, a container or canister for receiving and/or storing the lipoaspirate after removal from a patient. Lipoaspirate is delivered to the canister by means of an inlet orifice or valve, for example, connected to a source of negative pressure, or vacuum. Alternatively,

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lipoaspirate may be delivered to the canister without using suction, for example, by pouring the lipoaspirate into the canister through a top opening, for example. The canister may also include an outlet orifice or valve for facilitating removal of the desired, processed material, for example, a material primarily comprising viable fat cells.

The device further includes a separation mechanism structured to separate both oils and other materials from cellular components of lipoaspirate contained in the canister. The separation mechanism comprises, for example, one or more filter elements, for example, a sieve or filter screen for separating viable fat cells from damaged cells, oils, and other liquids. For example, the filter screen, or sieve, may comprise any number of known materials that are capable of sorting or dividing components by size. For example, the filter element may comprise a filter paper having a suitable pore size, a mesh with varying pitch, or other material known in the art capable of separating lipoaspirate components.

The device further comprises an activation mechanism structured to activate the separation mechanism. For example, the activation mechanism is structured to move at least one of the first and the second filter elements within the canister. The activation mechanism may comprise one or more plunger mechanisms, slidably contained in the canister and coupled to the filter elements. The one or more plungers may be operable by means of a piston, for example, and function to move the one or more filter elements within the canister. The plungers may be manually operable.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may be more clearly understood and the advantages thereof better appreciated by considering the below Detailed Description and accompanying Drawings of which:

FIG. 1 is a simplified diagrammatical view of a device, in accordance with the invention, having two independently movable filter screens for separating components of lipoaspirate.

FIGS. 2A-2D show operation of the device shown in FIG. 1.

FIG. 3 shows an alternative device, in accordance with the invention, including a fixed filter screen.

FIG. 4 shows yet another device in accordance with the invention.

FIGS. 4A-4C show operation of the device shown in FIG. 4.

FIGS. 5 and 6 show mechanically limiting features for controlling rate of filtering.

DETAILED DESCRIPTION

Turning now to FIG. 1, an exemplary device 10 in accordance with an embodiment of the invention is shown. The device 10 generally includes a canister 12 for containing lipoaspirate, an inlet 14, and outlet valve 16 and a separating mechanism 18 including first and second filter screens 20a, 20b and plungers 22 which are movable, for example, by manual means, in the canister 12.

The operation of the device 10 is shown in FIG. 2A-2D.

Lipoaspirate 24 is brought into canister 12, for example, drawn into the canister 12 by vacuum mechanism 28 through inlet 14 (FIG. 2A). The plungers 22 may be manually driven by a physician/operator applying force to plungers 22 as illustrated by arrows (FIG. 2B). Driving of plungers 22 forces lipoaspirate materials which can pass through

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the filter screens **20a**, **20b** into spaces in canister **12** opposing the screens **20a**, **20b**, thus separating the materials making up the lipoaspirate **24**.

The filter screens may comprise any number of suitable materials capable of separating components of the lipoaspirate.

Advantageously, the present device **10** allows separation of lipoaspirate to a desired degree. For example, it may be desirable in certain circumstances, as determined by the physician/operator, to remove a portion of the liquids, for example, oils, from the viable cells, leaving a minor amount or desired percentage of oil in the lipoaspirate for promoting fat graft viability. The simplicity of device **10** allows the physician/operator to control the degree or amount of separation. To further facilitate this feature, the canister **12** may be structured or made of a material, for example, a transparent polymer, that allows the physician/operator to view the content of the canister **12**.

As the filter screens **20a**, **20b** are driven through the lipoaspirate, the lipoaspirate is separated into various components. For example, blood/tumescent fluid **24a** are forced through first filter **20a**, while oil **24b** is forced through the second filter **20b**. (FIG. 2C). After sufficient separation is achieved, viable fat cells **24c** and any remaining blood/tumescent fluid and/or oils, can be removed via the outlet valve **16** (FIG. 2D).

FIG. 3 shows a device **110** in accordance with another embodiment of the invention. For the sake of simplicity, elements of device **110** which are similar or identical to elements of device **10** are indicated by the same reference number increased by 100.

Device **110** is similar to device **10**, with a major distinction being that device **110** includes a single plunger **122** rather than multiple plungers, and a fixed filter screen **120a**. Device **110** includes first and second screens **120a**, **120b** for separating blood/fluid and oils from fat cells. In this embodiment, the first filter screen **120a** is fixed within the canister **112**, while second filter screen **120b** is movable in canister **112** by means of plunger **122**. Outlet **116** may be positioned on an upstream side of fixed filter **120a**, as shown. The physician/operator causes separation of lipoaspirate within the canister **112** by pressing on the plunger **122**. Movement of second filter screen **120b** into the lipoaspirate causes separation of the lipoaspirate as described elsewhere herein, leaving viable fat cells between the first and second filter screens **120a**, **120b**, which can be removed from canister via outlet **116**.

FIG. 4 shows yet another device **210** in accordance with the invention. For the sake of simplicity, elements of device **210** which are similar or identical to elements of device **10** are indicated by the same reference number increased by 200.

Device **210** includes inlet **214** and outlet **216** both located on a common side of first and second filter screens **220a**, **220b**, for example, at a bottom side of the canister **212**. This arrangement may eliminate the sensitivity associated with placing the inlet and outlet valves on the canister in a specific location (which may be dependent on how much and the type of lipoaspirate that is sampled. This arrangement ensures that all incoming fluid is below both filter screens **220a**, **220b**, and allows for effective drainage of tumescent fluid, which has a relatively high density, followed by complete removal of viable fat.

Exemplary operation of device **210** is illustrated in FIGS. 4A-4C. First and second filter screens **220a**, **220b**, are oriented such that first screen **220a** and second screen **220b** are initially directly adjacent one another (FIG. 4). Due to

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arrangement of plunger heads, one overlapping the other, pressure on first plunger **222a** (shown as left plunger in the Figures) moves both first and second screens **220a**, **220b** into lipoaspirate **24** and causes separation of the oil **24b** therefrom (FIG. 4A). Second plunger **222b** is then pressed, independently of first plunger **222a**, which moves only first filter screen **220a** and filters out the blood and tumescent fluid **24a** (FIG. 4B). The viable fat cells **24c** are then removed through the outlet valve **216** (FIG. 4C).

Turning now to FIG. 5, any of the aforementioned embodiments may further comprise a mechanically limiting feature for controlling filtering rate. The amount of stress applied to lipoaspirate may affect the viability of the lipoaspirate cells. Thus, in some embodiments, a mechanism is provided to control the acceleration of the plunger through the lipoaspirate and/or reduce the speed at which the filter screens are forced through the lipoaspirate. For example, the mechanically limiting feature comprise, for example, any suitable mechanism, for example, spring **46**, or the like, coupled to plunger **22**, **122**, **222a** and/or **222b**. The spring **46** controls the movement of the plunger, for example, by providing a dampening effect, thereby allowing a slower and/or more consistent motion of the filter screen through the lipoaspirate, thereby reducing damage to cells. Alternatively, the mechanically limiting feature may comprise a hydraulic mechanism **48** for controlling plunger rate, such as shown in FIG. 6.

In another aspect of the invention, a method for treating lipoaspirate for use in fat grafting procedures is provided wherein the method comprises containing lipoaspirate in a container, the container including a first filter element and a second filter element, and moving the first filter element relative to a second filter element within the container to separate cellular components of the lipoaspirate from non-cellular components of the lipoaspirate. As mentioned elsewhere herein, the first filtering element may have a pore size different from a pore size of the second filtering element. Further, in some embodiments the first filtering element is capable of separating blood/tumescent fluids from cellular materials in lipoaspirate, and the second filtering element is capable of separating oils from cellular materials in lipoaspirate. In some embodiments, the container allows for viewing of the lipoaspirate during the separation, and the method may involve the step of observing the separation and stopping the moving when a desired degree of separation is achieved.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the invention.

What is claimed is:

1. A device for treating lipoaspirate for use in fat grafting procedures, the device comprising:

a canister for containing lipoaspirate;

a separation mechanism structured to separate both oils and other materials from cellular components of lipoaspirate contained in the canister, the separation mechanism comprising:

a first filter element disposed within the canister, and a second filter element disposed within the canister, and

an activation mechanism structured to activate the separation mechanism by moving the first filter element relative to the second filter element within the canister to separate cellular components from non-cellular components of the lipoaspirate; and

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an inlet and an outlet, both the inlet and the outlet being located on a common side of the first and second filter elements between the first and second filter elements.

2. The device of claim 1 wherein the activation mechanism comprises a plunger.

3. The device of claim 1 wherein the first filtering element has a pore size different from a pore size of the second filtering element.

4. The device of claim 1 wherein the first filtering element is capable of separating blood/tumescent fluids from cellular materials in lipoaspirate.

5. The device of claim 1 wherein the second filtering element is capable of separating oils from cellular materials in lipoaspirate.

6. The device of claim 1 wherein the activation mechanism comprises a manually operable piston and a mechanical limiting feature coupled to the piston.

7. A device for treating lipoaspirate for use in fat grafting procedures, the device comprising:

a canister for containing lipoaspirate;

a separation mechanism structured to separate oils or other materials from cellular components of lipoaspirate contained in the canister, the separation mechanism comprising first and second filter elements disposed within the canister;

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an activation mechanism structured to activate the separation mechanism by moving the first filter element and the second filter element relative to the canister to separate cellular components from non-cellular components of the lipoaspirate; and

an inlet and an outlet, both the inlet and the outlet being located on a common side of the first and second filter elements.

8. The device of claim 7, wherein the activation mechanism comprises a plunger.

9. The device of claim 7, wherein the first filtering element has a pore size different from a pore size of the second filtering element.

10. The device of claim 7, wherein the first filtering element is capable of separating blood/tumescent fluids from cellular materials in lipoaspirate.

11. The device of claim 7, wherein the second filtering element is capable of separating oils from cellular materials in lipoaspirate.

12. The device of claim 7, wherein the activation mechanism comprises a manually operable piston and a mechanical limiting feature coupled to the piston.

13. The device of claim 7, wherein the inlet and the outlet are disposed between the first and second filter elements.

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